IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-286-GMS
BARR LABORATORIES, INC.	)	
Defendant.	)	

PLAINTIFFS' ANSWERING BRIEF ON CLAIM CONSTRUCTION

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INTRODUCTION

Barr accuses Aventis of construing contested claim language without considering the intrinsic evidence, but Barr itself pays no attention to the two most important sources of the meaning of the terms at issue: the claims themselves and the knowledge of one of ordinary skill in the art. Even Barr recognizes that "[t]he starting place in claim construction is the language of the claims themselves," but Barr makes no attempt to reconcile its proposed constructions with the context of any claims, let alone all of the claims. D.I. 116 at p. 5, (hereinafter"Barr's Opening Brief"). Indeed, *Barr failed to include even a single full claim in its Opening Brief*. Similarly, Barr makes no attempt whatsoever to consider the knowledge of one of ordinary skill in the art; it reviews the intrinsic evidence from the point of view of a layperson and considers only general dictionaries as extrinsic evidence. *Compare* Barr's Opening Brief, p. 5 ("Claim terms are usually given 'their ordinary and customary meaning,' which is 'the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.') *to id.*, p. 21, 37, and 39. When the claims as a whole are considered, and construed from the point of view of one of ordinary skill in the art, there is no question that only Aventis's constructions can be correct.

In its brief, Barr cites continually to *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), as establishing rules for claim construction. Even as it does so, Barr violates several of the rules established and applied in *Phillips*. As discussed in more detail below, Barr fails to (i) consider the construction of the claims from the point of view of one of ordinary skill in the art, (ii) start the claim construction process with the language of the claims themselves, and (iii) interpret the claim terms consistently

throughout the claims, specification, and prosecution history. *Phillips*, 415 F.3d at 1314-1315. As a result of all of these failures, Barr's claim construction process is flawed.

The result of Barr's flawed claim construction process is nonsensical. Because it ignores the context of the claims, Barr construes several claim terms as imposing the same limitations, which *Phillips* makes clear is inappropriate. The error in Barr's approach can be seen by replacing the contested claim terms "pharmaceutically effective amount" and "thixotropic" with Barr's proposed constructions in claim 1 of the '573 patent (redundant language is emphasized in the same manner):

> An aqueous pharmaceutical composition which is capable of being sprayed into the nasal cavity of an individual and which comprises:
>
> (A) [an amount] of solid particles of triamcinolone acetonide [that exerts pharmacological action and provides relief of nasal symptoms caused by the abnormal bodily condition] which is effective in treating an abnormal bodily condition by virtue of its being present on the mucosal surfaces of the nasal cavity; and
>
> (B) a suspending agent in an amount effective to maintain said particles dispersed uniformly in the composition and to impart to the composition the following [At rest, the composition is a gel with a setting viscosity (or viscosity at rest) that is sufficiently high to hold and maintain the particles of TAA suspended and dispersed uniformly in the composition. The composition has a shear viscosity (or viscosity when shaken) that becomes lower than the setting viscosity and sufficiently low to maintain the particles suspended in the composition and to permit the composition to flow freely through the pump orifice and to break up into a fine mist that readily enters the nasal passages and deposits on the mucosal surfaces of the nasal cavity. Upon immediate contact with the mucosal surfaces, the composition returns to a gel and to its setting viscosity, which is sufficiently high to maintain particles of medicament suspended therein and to retain for an extended period of time the composition on the mucosal surfaces of the nasal cavity (including the anterior regions of the nose, frontal and maxillary sinuses and turbinates), i.e., the composition resists being swept away by the mucocillary forces present in the nasal cavity. That extended period of time must be greater than 30 minutes.] properties:

> (i) the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein; (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and (iii) in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity.

Barr's Opening Brief, page 9; A9-A10 ('573 Patent, col. 12, l. 59 – col. 13, l. 12). Furthermore, Barr's proposed claim construction would lead to numerous claims having the exact same scope, which again is inappropriate. *Phillips*, 415 F.3d at 1315 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004). Thus, the results of Barr's improper claim construction process are erroneous interpretations.

ARGUMENT

A. "Aqueous pharmaceutical composition"

After the parties' opening briefs were filed, Barr agreed to accede to Aventis's construction of the claim term "aqueous pharmaceutical composition." Accordingly, the parties now agree that an "aqueous pharmaceutical composition" is "a water-based combination of ingredients comprising a medicament and other pharmaceutically acceptable ingredients, that is, materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation."[1] That construction is taken *verbatim* from the specification of the patents-in-suit, and is consistent with the ordinary and customary meaning of the term to

[1] Barr's agreement to this construction was contingent upon Aventis agreeing that Flonase, Beconase AQ, and Vancenase AQ are aqueous pharmaceutical compositions within the meaning of the claims of the '573 and '329 patents. Aventis has never asserted that those products fail to meet the "aqueous pharmaceutical composition" limitation, but does submit that they fail to meet other claim limitations.

one of ordinary skill in the art. A5 ('573 Patent, col. 3, l. 45-50) and A16 ('329 Patent, col. 3, l. 54-59); *see also* D.I. 117 at p.17 (hereinafter "Aventis's Opening Brief").

B. "Mucosal Surfaces"

Since the submission of opening claim construction briefs, the parties have come to agreement on the construction of "mucosal surfaces." Specifically, Barr has accepted the offer Aventis made in footnote 2 of its Opening Brief: The parties agree that "mucosal surfaces" means "the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates, and the maxillary and frontal sinuses" and that the term does not give rise to any written description or indefiniteness defense under 35 U.S.C. § 112. *See* Aventis's Opening Brief, p. 19 n.2. Despite that agreement, there may still be some disagreement as to the importance of the term "mucosal surfaces" – despite its construction, Barr argues in its Opening Brief that the claims all require, either expressly or impliedly, deposition of the claimed composition on each of the mucosal surfaces. Barr's Opening Brief, at 33-34. Under Federal Circuit precedent, including *Phillips*, that cannot be correct: the express requirement in some claims of deposit on "each of" the mucosal surfaces means that the other claims that do not have such an express requirement do not require deposition on "each of" the mucosal surfaces. *Philips,* 415 F.3d at 1314-15.

It is undisputed that some of the claims of the '573 and '329 patents call for deposition of the composition on "*each of* the mucosal surfaces of the anterior regions of the nose, the frontal sinus and the maxillary sinuses, and on *each of* the mucosal surfaces which overlie the turbinates covering the conchas." *See* Barr's Opening Brief, p. 33 n.8 (quoting D.I. 114, '573 Joint Claim Construction Chart, p. 8-9, 13 (emphasis added)). It

is equally undisputed that some claims omit the term "each of" and require only deposit on "the mucosal surfaces." *See, e.g.*, A10-A11 ('573 Patent, col. 14, l. 45-57, col. 15, l. 1-3). That is, it is clear that the Applicant recognized a difference between "each of the mucosal surfaces" and "the mucosal surfaces" and expressed that recognized difference where appropriate. The Federal Circuit has clearly held that the inclusion of an express limitation in some claims, as here, means that other claims should not be read as having an implied limitation in exactly the same manner. *Phillips*, 415 F.3d at 1325 (citing *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1123 (Fed. Cir. 2001)). Thus, the claims dictate that "the mucosal surfaces" does not mean "each of the mucosal surfaces" unless the further limitation is expressly part of the claims.

Barr attempts to justify its violation of the doctrine of claim differentiation by pointing to preferred embodiments in the specification. Of course, it is generally inappropriate to import a preferred embodiment into the claims of a patent. *Phillips*, 415 F.3d at 1323. But it is similarly incorrect to assert that every claim must embody all of the multiple objectives set forth in the written description of the patent. "The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures [or compositions] that are capable of achieving all of the objectives." *Liebel-Flarsheim*, 358 F.3d at 908 (quoted in *Phillips*, 415 F.3d at 1327). Here, there are several independent claims that satisfy the objective of depositing the claimed composition on "each of" the mucosal surfaces; other claims do not. Nothing in the specification or prosecution history specifically indicates that the invention is limited to only those formulations that deposit on "each of" the mucosal

surfaces, meaning that only the claims that expressly require deposition in all of those areas should be read as having such a limitation. Because Aventis's construction, not Barr's, gives meaning to all the claim language (including "*each of* the mucosal surfaces") and is consistent with the language of the specifications of the two patents-in-suit, Aventis's construction should be adopted by the Court.

C. "Pharmaceutically effective amount"

Barr's proposed construction of "pharmaceutically effective amount" is incorrect in attempting to include a limitation that it "provides relief of nasal symptoms caused by the abnormal bodily condition," D.I. 114 ('573 Joint Claim Construction Chart at 2), when an express limitation already exists requiring the composition to be "effective in treating an abnormal bodily condition." A9-A10 ('573 Patent, Claim 1, col. 13, l. 63). That is, there is no doubt that the claimed composition must contain triamcinolone acetonide and be effective in treating an abnormal bodily condition, but those limitations are imposed elsewhere in the claims. *See, e.g.*, A9 ('573 Patent, Claim 1, col. 12, l. 62); A9 ('573 Patent, Claim 1, col. 12, l. 63). And because they are imposed elsewhere in the claims, it would be erroneous to read them into the term "pharmaceutically effective amount." *Phillips*, 415 F.3d at 1314-15, 1325. Without those added limitations, Barr's proposed construction would be the same as Aventis's; Aventis's construction should therefore be adopted.

Beginning from the vantage point of a person of ordinary skill in the art, Aventis has construed "pharmaceutically effective amount" in the context of the language of the claims in their entirety. It is not appropriate to construe claim language based on a portion of the claims. *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir.

2003) (quoted in *Phillips*, 415 F.3d at 1314). In highlighting the need to consult other language of the claims when construing particular claim terms, the Court in *Phillips* pointed out how language within claims can inform a reader as to the proper construction of terms in a claim: "To take a simple example, the claim in this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel." 415 F.3d at 1314; *see also, e.g., Mars, Inc. v. H.J. Heinz Co.,* 377 F.3d 1369, 1374 (Fed. Cir. 2004); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1356 (Fed. Cir. 1999).

As shown above, it would make no sense to adopt Barr's proposed construction because that would make the language of the claims redundant. *See supra* at 2-3. Just as the Court in *Phillips* refused to accept a construction that would render a claim to redundantly read "steel steel baffles," it would make no sense to construe the claim term "pharmaceutically effective amount" as Barr has proposed, which would render the claim in the current case to read as follows:

> an amount of solid particles of triamcinolone acetonide that exerts the pharmacological action and **provides relief of nasal symptoms cause[d] by the abnormal bodily condition** which is **effective in treating an abnormal bodily condition** by virtue of its being present on the mucosal surfaces of the nasal cavity."

Barr's Opening Brief at 39; A9 ('573 Patent, Claim 1, col. 12, l. 62-65). That is, Barr's construction does not lend meaning to each word of the claim language, but rather renders a significant portion of the claim language to be mere surplusage, in clear violation of the canons of claim construction. *See, e.g., Texas Instruments, Inc. v. United States Int'l Trade Commission*, 988 F.2d 1165, 1171 (Fed. Cir. 1993). Aventis's construction, on the other hand, is consistent with the entirety of the claim language.

Nothing in the specification or prosecution history suggests that the additional meaning of "provid[ing] relief of the abnormal bodily condition" should be poured into the term "pharmaceutically effective amount." In the only instance in which efficacy of the composition was addressed, it was discussed in terms of the medicament itself – not the amount of medicament – being effective. A4 ('573 Patent, col. 1, l. 6-8) (the invention "relates to an aqueous composition containing a medicament that is effective in treating an abnormal bodily condition."). Thus, there is nothing in the intrinsic evidence to impose an additional limitation on the term "pharmaceutically effective amount."

Barr's argument is notable for another reason: Barr obtains its definition from Webster's dictionary. Completely contradicting its argument alleging impropriety of considering extrinsic evidence relating to the claim term "thixotropic," Barr embraces extrinsic evidence here when it suits Barr's needs. *See* Barr's Opening Brief, p. 39 (citing Webster's); *compare Phillips*, 415 F.3d at 1317-18 ("authoriz[ing] district courts to rely on extrinsic evidence," especially technical dictionaries and treatises), 1322-23 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996), with approval regarding use of dictionaries and technical treatises). However, Barr's choice of a general dictionary as extrinsic evidence does not enlighten the Court as to how one of ordinary skill in the art would use the claim term "pharmaceutically effective amount"; it instead only supports how a layman would understand the individual word "effective." *See id.* at 1321-22 (criticizing use of general use dictionaries as failing to focus on art-specific definitions). That is, Barr's argument supports the unremarkable proposition that extrinsic evidence can be considered by the Court, but goes astray by using a lay source and failing to consider the context in which the term is used.

D. Thixotropic

Barr's argument on construction of the term "thixotropic" is most surprising for how greatly it differs from the Court-ordered Joint Claim Construction Chart submitted by the parties. Not only does Barr now rely on evidence that it did not cite in relation to its proposed constructions in the Chart, it has adopted a wholly different definition for the term. *See* D.I. 114 ('573 Joint Claim Construction Chart, p. 2, 5; and '329 Joint Claim Construction Chart p. 1, 4 (indicating "The specific thixotropic properties are described in the claim at (i)-(iii)," which differ from claim to claim, and citing only "'573 File History, paper 4, pp. 10-12")).[2] As Aventis described in its Opening Brief, Barr proposed numerous different constructions of the term "thixotropic" in the Chart – it should not be permitted to change those differing proposed constructions now, in direct contravention of the Court's Order scheduling the filing of the Chart. Nor should it be permitted to rely on evidence it did not include as support for its numerous proposed constructions in the Chart.

Even if Barr's new proposed construction of "thixotropic" were considered, adopting it would be simply erroneous. Aventis's proposed construction of "thixotropic" takes into account an awareness that one of skill in the art would understand the ordinary and customary meaning of this term; Barr's does not. Aventis's construction makes sense in the context of the entire claims; Barr's does not. Aventis's construction makes sense in the context of the specification and prosecution history; Barr's does not. Therefore, the court should adopt Aventis's construction for this term.

[2] Barr provided other definitions and cited additional evidence in relation to other claims in the Joint Claim Construction Chart. However, there are numerous sources that Barr did not cite before, but seeks to rely upon now. *See, e.g.*, Barr's Opening Brief, p. 15-16 (citing A210-11, A215).

The reason why Barr is arguing so forcefully for its erroneous claim construction proposal becomes clear upon a careful reading of Barr's Opening Brief: Barr is seeking to incorporate the express limitations of claim 1 of the '573 patent into other claims in which those limitations do not appear, through a convoluted reading of "thixotropic." Thus, in its discussion of clause (iii) of claim 1, Barr contends, without citing any support, that "[t]his requirement applies equally to claim 34 of the '573 patent and claims 13, 14 and 25 of the '329 patent based on a proper construction of 'thixotropic.'" Barr's Opening Brief, p. 28 n.7. But the express inclusion of that clause (and other limitations) in claim 1 of the '573 patent means that it cannot be part of the proper construction of "thixotropic." *See Phillips*, 415 F.3d at 1324 ("The inclusion of such a specific limitation on [a claim term] makes it likely that the patentee did not contemplate that the term . . . already contained that limitation."). The Applicant intended different claims to have different scopes and included or excluded limitations to accomplish that goal; it would be erroneous to negate that choice by reading express limitations from one claim into other claims.

i. Only Aventis's Construction of "Thixotropic" Is Consistent with the Knowledge of One of Ordinary Skill in the Art

Aventis construes the term "thixotropic" by starting from the point of view of one of ordinary skill in the art. In contrast, Barr ignores the fact that one of ordinary skill in the art would have a preconceived definition of the term to reach its faulty proposed construction of "thixotropic." As *Phillips* noted,

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field.

. . .

> Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and *extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art*.

Phillips, 415 F.3d at 1313-14 (emphasis added; citations and internal quotations omitted). That is, far from scorning consideration of extrinsic evidence to determine the ordinary and customary meaning of a technical claim term, the Federal Circuit encourages it. Aventis cited just such extrinsic evidence – from a well-accepted treatise – as an indication that one of skill in the art would know and understand the ordinary and customary meaning of the claim term "thixotropic." Aventis's Opening Brief, pp. 23-24. Barr retreats from the person of ordinary skill in the art and instead starts from the proposition that the reader would be *tabula rasa*, having no knowledge of a specialized meaning in the art for the term "thixotropic." Under Barr's approach, a layman would construe the claims from reading only the specification and prosecution history. Barr's Opening Brief, pp. 9-17. That approach cannot be correct.

Barr correctly notes that extrinsic evidence cannot provide a controlling definition different from that set forth in the claims, specification, and prosecution history, but as discussed below, Aventis's definition is wholly consistent with the claims, specification, and prosecution history. *See* Barr's Opening Brief, pp. 17-19. In such a case, *Phillips* noted,

> Within the class of extrinsic evidence, the court has observed that dictionaries and treatises can be useful in claim construction. We have

> especially noted the help that technical dictionaries may provide to a court to better understand the underlying technology and the way in which one of skill in the art might use the claim terms.

Phillips, 415 F.3d at 1318. Thus, Aventis's citation of Barnes (A454 ("An Introduction to Rheology," by H.A. Barnes, J.F. Hutton, and K. Walters)) is wholly appropriate.

ii. Only Aventis's Construction of "Thixotropic" Is Consistent with the Claims

Barr starts its consideration of the construction of "thixotropic" with the specification, but that is itself erroneous. As the Federal Circuit noted in *Markman*, and cited with approval in *Phillips*,

> The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (cited by *Phillips*, 415 F.3d at 1312). That is, the claims (not the specification) are "of primary importance, in the effort to ascertain what it is that is patented."[3] *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) (quoted in *Phillips*, 415 F.3d at 1312). Claim 1 of the '573 patent and claim 6 of the '329 patent already require the claimed composition to have the following properties:

> (i) the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein;
>
> (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and

[3] Barr cites *Phillips* as indicating that the "claims are directed to the invention that is described in the specification" and that the "specification is 'the single best guide to the meaning of a disputed term." Barr Opening Brief, p. 1, 6. In both instances, *Phillips* is discussing the written description, *which includes the claims*. *Phillips*, 415 F.3d at 1315-1316; *see also* 35 U.S.C. § 112, ¶ 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.").

> (iii) in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity.

A9 – A10 ('573 Patent, col. 12, l. 59- col. 13, l. 12); A21 ('329 Patent, col. 13, l. 37-53).

Claim 1 of the '329 patent and claim 5 of the '573 patent require similar, but slightly different, properties:

> (i) the viscosity of the composition in unsheared form is about 400 to about 800 cp;
>
> (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition is about 50 to about 200 cp and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and
>
> (iii) in deposited form on the mucosal surfaces, the viscosity of the composition is about 400 to about 800 cp and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity . . . .

A21 ('329 Patent, col. 13, l. 2-26); A10 ('573 Patent, col. 13, l. 20-46).

The Court need only substitute Barr's proposed construction of the term "thixotropic" into the claims to see that Barr's proposed construction is inappropriate. As shown, *supra*, at pages 2-3 and discussed above in relation to the term "pharmaceutically effective amount," the result of doing so would render those already-existing limitations unnecessary if persons of skill in the art understood that the term "thixotropic" carried with it such limitations. *Phillips*, 415 F.3d at 1325 (citing *TurboCare*, 264 F.3d at 1123). *Phillips* provides another "simple example" of the same rule, stating, "[T]he claim in this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel." *Id.* at 1314. Thus, the inclusion of specific

properties in the claims means that those properties cannot be part of the definition of "thixotropic." Barr's proposed construction therefore cannot be correct.

iii. Only Aventis's Construction of "Thixotropic" Is Consistent with the Specification

The specification discloses preferred embodiments of the claimed invention, but never indicates that the claims should be limited to any of the specific embodiments. Importation of limitations from preferred embodiments into the claims is improper. *Id.* at 1323. Instead, as *Phillips* noted, "[I]f the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms," it can guard against importing limitations from preferred embodiments into the claims. *Id.* Even if the description of the preferred embodiments are quite specific, or if there is only one embodiment disclosed, the patent need not be limited to those disclosures. *Id.* Here, nothing in the passages that Barr cites suggests that the limitations proposed by Barr should be incorporated into the claims through the term "thixotropic." Quite to the contrary, several of the passages cited by Barr do not even discuss the thixotropic nature of the composition. *See* Barr's Opening Brief, pp. 11-12. Thus, while they may be describing claim limitations, they cannot be describing limitations that should be read into the term "thixotropic."

There is no doubt that the Applicant could have specifically, expressly defined the term "thixotropic" in the specification by stating what "thixotropic" *means*. Barr does not raise that argument because there is also no doubt that the Applicant did not do so. Rather, the linchpin of Barr's legal argument is that a description using the definite article "the" to describe the "composition of the present invention" means that the Applicant must have been defining the limitations of the claims. Barr's Opening Brief, p. 13 ("The

repeated use of the word 'the' to describe 'the composition of the present invention' and its thixotropic properties is definitive.").[4] The Federal Circuit recently heard such an argument and rejected it. *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007) ("[T]he written description states that the 'pharmaceutically acceptable polymer *is* . . .,' which does not as unambiguously signify that the description provided is definitional."). Barr's argument is simply wrong under Federal Circuit precedent.

Neither of the two cases cited by Barr suggests a different conclusion. *See* Barr's Opening Brief, p. 13 (citing *Honeywell Int'l Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1320 (Fed. Cir. 2006); *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1348 (Fed. Cir. 2004)). *Honeywell* certainly did not hold "that, when the patent expressly describes the 'present invention,' the scope of the claim cannot be broadened beyond this description," as Barr argues. Rather, *Honeywell* stands for the unsurprising proposition that when an applicant contrasts his invention with the use of other materials – going so far as to "demean" the use of the other materials in the specification – he cannot recapture the use of those other materials within the claims in litigation. *Compare* Barr's Opening Brief, p. 13 *to Honeywell*, 452 F.3d at 1319-20. In *Microsoft*, the applicant described "sending" and "receiving" information "over a standard telephone line" in both the specification and the prosecution history; the Federal Circuit simply found that the claims could not cover internet (packet-switched) communications. *Microsoft*, 357 F.3d at 1348-49. Neither

[4] Barr's argument contradicts other positions it takes in its Opening Brief. Barr argues that the Court should ignore *identical* wording in relation to the claim term "aqueous pharmaceutical composition." *Compare* Barr's Opening Brief, p. 37-38 to A5, col. 3, l. 44-49 ("The water-based composition of the present invention comprises . . . materials which are compatible with the medicament, which are not toxic to the body under the conditions of use and which avoid or minimize tissue irritation."). Clearly, not even Barr believes use of the word "the" is definitive.

case stands for the proposition that use of the word "the" to modify the description of the preferred embodiment of the invention is definitional.

Most egregiously, Barr attempts to slip in limitations on the construction of "thixotropic" that are not expressly or impliedly in the specification at all. First, nothing in the specification indicates that the composition "[u]pon immediate contact with the mucosal surfaces . . . returns to a gel." In fact, the word "immediate" never appears in the specification, the deposited product is never described as a gel, and a person of ordinary skill in the art would generally understand that the term "thixotropic" does not call for immediate recovery of viscosity. A454 ("An Introduction to Rheology," by H.A. Barnes, J.F. Hutton, and K. Walters). Had the Applicant wanted to alter the ordinary meaning of "thixotropic," he would have done so expressly and clearly – he did not do so. Thus, there simply is no basis for such a limitation. Second, nothing in the specification provides for a threshold retention time on the mucosal surfaces. It is notable that Barr's support for such a limitation is based solely on a single sentence, taken out of context, from a different section of the patent (the Field of the Invention), which Barr tries to tie to a description of the invention from the Detailed Description of the Invention. *See* Barr's Opening Brief, p. 12. Nothing in the Detailed Description of the Invention indicates that resistance of mucociliary clearance is tied to a specific time of residence, or that the general description of the claimed composition as "thixotropic" requires resistance. Instead, certain resistance to mucociliary forces is expressly recited in certain claims and not recited in others.

iv. Only Aventis's Construction of "Thixotropic" Is Consistent with the Prosecution History

Barr cites several instances in the prosecution history in which the term "thixotropic" was used, but both of those passages and other occurrences of the term make it absolutely certain that Barr's proposed construction is incorrect. Barr cites several passages from the prosecution history in which the inventor described the claimed composition as having defined "thixotropic properties" or a discussed "thixotropic nature." *See* Barr's Opening Brief, pp. 13-17. Aventis's construction of "thixotropic" is wholly consistent with those passages. Indeed, *only* Aventis's construction is consistent with the first passage cited by Barr, which concludes, "Applicant's claims include a definition of the thixotropic properties of the composition." Barr's Opening Brief, p. 14 (quoting A100). The Applicant did not say that the claims define the term thixotropic, but that the specific properties within the general class of thixotropy that describe the claimed composition are set forth in the claims. Claim 1 of the '573 patent and claim 6 of the '329 patent define the thixotropic composition as having specific properties in one way and claim 1 of the '329 patent and claim 5 of the '573 patent define the thixtropic composition as having specific slightly different properties, but all of those sets of properties fall within Aventis's construction of "thixotropic." The differences between those two sets of properties (and those in other claims as well) would indicate that Barr's proposed construction is incorrect.

Similarly, Barr relies on a passage in which the Applicant indicated,

> Although [two prior art] articles disclose a *thixotropic* aqueous intranasal formulation of triamcinolone acetonide for use in treating allergic rhinitis, the following claimed elements are not disclosed: . . . a suspending agent for dispersing the solid particles of medicament and for imparting to the

> composition the *thixotropic* properties which are defined in applicant's claims.

Barr's Opening Brief, p. 15 (quoting A101-02 (emphasis added); citing A326, 334, 339, 347). But if the word "thixotropic" meant to the Applicant what Barr urges the Court to adopt as a construction, that sentence would make no sense. In such a case, all of the physical properties set forth in the claim would be poured into the word "thixotropic," and the Applicant's description of the articles would mean that they ***did*** disclose that claim element. In contrast, Aventis's proposed construction makes perfect sense if substituted into that sentence: the prior art articles disclose formulations having some general properties within the ordinary meaning of the term "thixotropic" but do not disclose those specific physical properties (also within the scope of the general term "thixotropic") defined in the claims.

Barr's final citation to the prosecution history was to the Examiner's reasons for allowance, which included a statement that "the claimed composition comprising unique thixotropic properties, with specific viscosity traits (sheared and/or unsheared), and further comprising triamcinolone acetonide as medicament was not explicitly taught or suggested by the prior art of record." Barr's Opening Brief, pp. 15-16 (quoting A215). Contrary to Barr's proposed construction, by separating the reasons for allowance into three parts, the Examiner clearly indicated that use of the term "thixotropic" did not indicate "specific viscosity traits (sheared and/or unsheared)" or "triamcinolone acetonide as medicament." Thus, even the passages from the prosecution history cited by Barr prove that Barr's construction is incorrect.

Other passages in the prosecution history make it even clearer that Barr's lengthy definition of "thixotropic" – limited to triamcinolone acetonide as the medicament, pump

delivery to the nasal cavity, immediate viscosity recovery, and threshold retention time on the mucosal surfaces – is incorrect. Barr cites to a discussion of other drugs that the Applicant brought to the Examiner's attention in an Information Disclosure Statement ("IDS"), wherein the Applicant indicated that his "recent tests on such prior art compositions have shown that such prior art compositions exhibit thixotropic properties." Barr's Opening Brief, p. 15 (quoting A210-11). Those prior art compositions do not include triamcinolone acetonide as the medicament, taking them outside Barr's proposed construction of the term "thixotropic." Similarly, an earlier IDS described numerous patents as including thixotropic compositions,[5] even if the compositions were not intended for nasal use, spraying, or even human use:

> U.S. Patent No. 4,427,681 to Munshi
>
> This patent discloses an aqueous-based pharmaceutical composition which is convertible from a thixotropic gel to a pourable liquid upon moderate shaking for about 5 seconds. The patent describes the use of microcrystalline cellulose in combination with sodium carboxymethylcellulose as a suspending agent for thixotropic pharmaceutical compositions. The composition is disclosed as being suitable for use as a cough syrup.
>
> U.S. Patent No. 5,300,302 to Tachon et al.
>
> This patent discloses a pharmaceutical composition suitable for ingestion via the oral cavity, the composition being in gel syrup form and packaged in a metering dispenser. The active ingredient of the composition is homogeneously distributed in a thixotropic pseudoplastic water-dispersible gel which does not run during dispensing.
>
> . . .

[5] Aventis did not cite this portion of the prosecution history in the Joint Claim Construction Chart in support of its construction of "thixotropic." However, it clearly rebuts Barr's arguments, which are based on a portion of the prosecution history that Barr did not cite in the Joint Claim Construction Chart.

> U.S. Patent No. 3,035,984 to Mierswa
>
> This patent discloses pharmaceutical compositions comprising aqueous suspensions of water-insoluble drugs for administration either orally or by injection. This patent discloses the use of a thixotropic agent obtained from seaweed.
>
> U.S. Patent Nos. 5,432,147 and 5,432,148 to Winston et al.
>
> These patents disclose an aqueous fungicide composition for controlling fungal disease in plants. The fungicide contains a thixotropic agent which allows the viscosity of the fungicide to decrease with increasing shear rate.

A121, A123-24. That is, "thixotropic" is used in the prosecution history in relation to oral medications, injectibles, and fungicides for plants. All of these uses of the term are consistent with Aventis's construction; none is compatible with Barr's.

In summary, Aventis's proposed construction of "thixotropic" is consistent with the knowledge of one of ordinary skill in the art, the claims, the specification, and the prosecution history. Barr's proposed construction is, remarkably, inconsistent with both the intrinsic and extrinsic evidence. Therefore, Aventis's construction should be adopted.

E. "The viscosity of the composition in unsheared form is relatively high with the composition being a gel having said particles suspended therein"

Although Barr tries to import the substance of this claim limitation into the meaning of the claim term "thixotropic" as well, which is improper, the parties agree for the most part on the construction of clause (i) of claim 1 of the '573 patent and claim 6 of the '329 patent. There are, however, two points of contention between the parties over the meanings of "relatively high" and "a gel having said particles suspended therein." *Compare* Aventis's Opening Brief, pp. 27-30 *to* Barr's Opening Brief, pp. 20-23. The specification provides the answer for "relatively high" and how to measure the "relatively high" viscosity, the prosecution history provides the answer for "a gel having said

particles suspended therein." Barr ignores the former, and simply refuses to construe the latter. Because Aventis's constructions are correct, this Court should adopt them.

Remarkably, in support of its argument on the meaning of the term "thixotropic," Barr cites the very language from the specification that defines the term "relatively high." *See* Barr's Opening Brief, p. 10 (quoting A5 ('573 Patent col. 4, l. 39-41) (in section on "The Specification Provides The Definition Of The Thixotropic Properties Of The Composition")). Specifically, Barr itself argues that there is only one embodiment of the invention, one in which, among other things, "[t]he viscosity of the composition at rest is relatively high, for example, about 400 to about 1000 cp."[6] *Id.* Thus, when it suits Barr, Barr argues that the claims require an absolute definition of "relatively high." When it comes to clause (i) of claim 1 of the '573 patent and claim 6 of the '329 patent, however, Barr now suggests a wholly different definition. That is improper. *Southwall Techs. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995).

Barr argues that Aventis is bound by the Applicant's proposed definition of "relatively" (low and high) in the prosecution history in response to an indefiniteness rejection. *See* Barr's Opening Brief, pp. 22-23. Had the Examiner accepted the Applicant's definition, Barr would be correct that the Applicant's proposed definition would control. But the Examiner refused to accept the Applicant's definition – after the Applicant proposed the relative definition, the Examiner *twice* maintained his indefiniteness rejection relating to the term "relatively" and demanded that the Applicant

[6] The specification's indication that the range of viscosities is exemplary would normally indicate that the range is not definitional. *See Phillips*, 415 F.3d at 1323; *see also* A5 ('573 patent col. 4, l. 39-41); A16 ('329 patent col. 4, l. 48-50). However, given the Examiner's requirement that a range be defined, and his finding that range only in the specification, it is clear that he required the range of viscosities from the specification to be a definition.

supply a viscosity "range that defines the criteria" of "relatively" low and high. A112 (Maintaining § 112 rejection because "[t]he terms [*sic*] 'relatively' is indefinite because the range that defines this criteria is not defined."); A147 ("Claim [1] is rejected under 35 U.S.C. § 112, second paragraph as previously discussed in the Office Action mailed 5/15/97. The terms [*sic*] 'relatively' is indefinite because the range that defines this criteria is not defined."). As Barr recognized in its Opening Brief, "The public has a 'right to rely' on statements as to the scope of the invention made in the prosecution history as well as the Examiner's reasons for allowing the claims." Barr's Opening Brief, p. 16 (citing *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1347 (Fed. Cir. 1998)). Faced with the Examiner's steadfast refusal to accept "relatively high" as being a relative measure, the Applicant retreated and accepted that the term had to be defined in an absolute manner, as had been done in an example in the specification. A5 ('573 patent col. 4, l. 39-41); A16 ('329 patent col. 4, l. 48-50). The Examiner held an interview with the Applicant, then memorialized that the reasons for allowance included that "the claimed composition comprising unique thixotropic properties, *with specific viscosity traits (sheared and/or unsheared)*, and further comprising triamcinolone acetonide was not explicitly taught or suggested by the prior art of record in this application." A215 (emphasis added). That is, the Examiner clearly and unequivocally required narrow absolute values for "relatively high" and "relatively low" and would not allow the patent to issue until the Applicant abandoned his attempt to define those values more broadly, relative to one another. Barr's construction cannot be correct if the public is to rely on the Examiner's statements. The only defined range of viscosity for "relatively high" is the one in the specification.

Next, without expressly recognizing it, Barr appears to agree that the method for measuring that viscosity is defined by the specification. *See* Barr's Opening Brief, p. 31 ("The testing conditions, again, are partially set forth in the specification."). Because measurement of viscosity requires shearing a fluid, the method of measurement of viscosity inherently affects the viscosity of a thixotropic fluid.[7] The specification provides:

> Viscosity is measured using a Brookfield Synchro-Letric viscometer (Model LVT). The viscosity is measured at 20º C. The setting viscosity is measured after mixing at 30 rpm for 30 seconds. The shear viscosity is measured by mixing at 30 rpm for 30 seconds after mixing on a Burrell wrist-action shaker at full speed for 5 minutes.

A6 ('573 Patent, col. 5, l. 18-24); A17 ('329 Patent, col. 5, l. 27-33). Because measured viscosity of a thixotropic fluid is dependent on method of measurement, it would be improper to leave out the express requirement that the "relatively high" viscosity be determined according to the methodology set forth in the specification.

Finally, Barr attempts to take Aventis to task for not including the word "gel" within its construction of clause (i) of claim 1 of the '573 patent and claim 6 of the '329 patent. Ironically, Barr does not really define the term "gel having said particles suspended therein," it merely parses out the word "gel" and separately ascribes the suspension of the particles to the viscosity of the composition. Barr's Opening Brief, p. 20, 23. As discussed in Aventis's Opening Brief, the specification establishes that the suspension of the particles is the attribute that makes the composition a gel. Aventis's Opening Brief, pp. 29-30. Defining a "gel" as a "gel" does nothing to provide meaning

[7] For a Newtonian fluid, such as water, shearing neither thickens nor thins the fluid. Thus, the viscosity of Newtonian fluids can be measured by any means without affecting the value of the measurement. For non-Newtonian fluids, such as thixotropic suspensions, shearing changes the viscosity of the fluid. As a result, the act of viscosity measurement itself affects the value of the measurement.

to the claims, but Aventis's ordinary meaning construction provides clarity to the term. Indeed, in a different portion of its Opening Brief, Barr cites the very portion of the prosecution history that requires the construction of "a gel having said particles suspended therein" in the manner Aventis contends. Barr Opening Brief, p. 10 (quoting A5 ("The thixotropic nature of the composition at rest (not subject to shear) can be described as a gel in which the particles of medicament are dispersed and suspended substantially uniformly.")). Thus, a "gel having said particles suspended therein" should be construed as requiring the particles of medicament to be dispersed substantially uniformly in the composition.

Any question that "gel having said particles suspended therein" should be defined only in terms of holding particles dispersed substantially uniformly therein was resolved in the prosecution history. The Applicant originally indicated that the unsheared state of the claimed composition was "gel-like," a description that the Examiner rejected as indefinite. A82. The Applicant therefore amended the claim language to "define the gel-like form of the composition as having suspended therein the solid particles of medicament." A108. In light of that clarifying amendment and definition, the Examiner indicated that the claim would be definite as long as the term "gel-like" was changed to "gel." A112; A147. As a result, only Aventis's construction is supported by the intrinsic evidence.

F. "As the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity"

As with clause (i) of claim 1 of the '573 patent and claim 6 of the '329 patent, the parties agree for the most part on the construction of clause (ii) of claim 1 of the '573

patent and claim 6 of the '329 patent.[8] Their point of contention is the meaning of "relatively low" viscosity and, potentially, how to measure that viscosity. Both of those claim construction issues are resolved by the intrinsic evidence that dictates the numerical meaning of "relatively high" and the method of measurement for clause (i). *See* A5-6 ('573 Patent, col. 4, l. 63-col. 5, line 6) & A17 ('329 Patent, col. 5, l. 15-18);[9] A112; A147; A215; A6 ('573 Patent, col. 5, l. 18-24) & A17 ('329 Patent, col. 5, l. 27-33). Thus, "relatively low" viscosities should be construed to be those that range from about 50 to about 200 centipoises when measured by the method disclosed in the specification.

G. "In deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity"

Only Aventis's construction of the term "in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity" is consistent with how one of skill in the art would understand the claim term. Moreover, Barr's proposed definition does not take into account the context in which the terms appear in the claims. As such, Aventis's construction should be adopted by this court.

[8] The parties have the same potential dispute over the method of measurement in relation to clause (i) of claim 1 of the '329 patent and claim 5 of the '573 patent. *See* D.I. 114 ('573 Joint Claim Construction Chart p. 5; '329 Joint Claim Construction Chart, p. 2).

[9] "As the composition is subjected to shear forces, for example, upon being subjected to forces involved in its being agitated before spraying, the viscosity of the composition decreases (for example, to about 50 to about 200 cp) and it flows readily through the spray device and exits therefrom in the form of a fine plume . . . ."

Barr's first error is asserting that construction of clause (iii) of claim 1 of the '573 patent and claim 6 of the '329 patent requires return to the original setting viscosity in deposited form. Clause (iii) of those claims uses the same term – relatively high – to describe the eventual deposited viscosity as it does to describe the unsheared viscosity of clause (i), but clause (iii) never indicates that the viscosity must be the same as the original unsheared viscosity. *See* A10 ('573 Patent, Claim 1, col. 13, l. 8-12); A21 ('329 Patent, Claim 6, col. 13, l. 54-59). Rather, clause (iii) requires only that, at some point, the deposited form of the composition have a viscosity that is "relatively high." That is, Aventis agrees that "relatively high" should have the same construction in clause (iii) that it has in clause (i), but that means only that at some point while deposited, the viscosity must be within the range between from about 400 to about 1000 centipoises. *See supra* at 20-23. The "relatively high" viscosity recited in clause (i) and clause (iii) need not be numerically identical.

Barr apparently seeks to impose even more limits on the "relatively high" viscosity: that there be only one "deposited" viscosity, and that the "deposited" viscosity be exactly the same as the unsheared viscosity. Nothing whatsoever in the specification or prosecution history supports that position. Barr cites only to a passage of the specification that discusses the viscosity at rest and the shaken viscosity, arguing that it should apply by inference or extension to a deposited viscosity. *See* Barr's Opening Brief, pp. 26-27 (quoting A5-6). However, nothing in Barr's cited passage indicates that the Applicant intended to limit the scope of the claims (as opposed to describing a preferred embodiment). Furthermore, a mere inference that a viscosity upon deposition was being described is far from an unambiguous intent to have defining characteristics of

viscosity read into the claims. *Phillips*, 415 F.3d at 1323. There simply is no basis to limit the viscosity on deposition in that manner.

Barr's next error lies in asserting that the deposited composition must, "[u]pon immediate contact with the mucosal surfaces . . . return[] to a gel." *See* Barr's Opening Brief, pp. 25-30. At no point do the claims, specification, or prosecution history state that the deposited composition must change viscosity immediately or become a "gel." To the contrary – although clause (i) of claim 1 of the '573 Patent and claim 6 of the '329 Patent requires the unsheared state of the composition to be a "gel," clause (iii) does not use that term. It is just as erroneous to read an unexpressed limitation into a portion of a claim when the limitation is expressly required by another portion of the claim as it would be to read a limitation into a claim "where another claim restricts the invention in exactly the [same] manner." *See Phillips*, 415 F.3d at 1325 (quoting *TurboCare*, 264 F.3d at 1123). Barr attempts to make up for that conflict between the language of the claims and its construction through grammatical legerdemain.

Finally, Barr attempts to impose a limitation that the claimed composition resist being cleared for at least 30 minutes. Again, nothing whatsoever in the specification defines the invention as being limited to compositions that resist clearing for at least 30 minutes. Instead, Barr tries to reason from a general description of physiological functioning of the nose. *See* Barr's Opening Brief, p. 30. That certainly is not enough to be considered a definition of any claim term. *Phillips*, 415 F.3d at 1323. But just as importantly, when the claims intend to ascribe a specific time limitation to resistance of mucocillary clearance, they do so. *See, e.g.*, A11 ('573 Patent, Claim 34); A21 ('329 Patent , Claim 17). The express inclusion of a temporal limitation in other claims

suggests that it is not imposed implicitly in clause (iii) of claim 1 of the '573 patent and claim 6 of the '329 patent. *Phillips*, 415 F.3d at 1323. Thus, no such limitation should be imposed, whether on the term "thixotropic" or clause (iii).

Instead, the specification simply provides that "[i]n deposited and relatively unstressed form, the composition increases in viscosity and assumes its gel-like form which includes particles of the medicament suspended therein and which resists being cleared from the nasal passages by the inherent mucocillary forces that are present in the nasal cavities." '573 Patent, col. 4, lines 54-59.

CONCLUSION

Because Barr's arguments do nothing to disprove that the Applicant intended the claims to be construed in the manner proposed by Aventis, this Court should adopt Aventis's proposed constructions of the contested terms. Specifically, Aventis proposes the contested terms be construed as follows:

Disputed Claim Term	**Aventis's Construction**
Pharmaceutically effective amount	An amount that exerts the pharmacological action of the medicament
Thixotropic	"Thixotropic" refers to the characteristics of a composition which exhibit a decrease in apparent viscosity due to shear force, followed by a gradual time-dependent recovery of apparent viscosity when shear force is removed
the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein	The viscosity of the composition at rest during non-use is sufficiently high to hold and maintain the particles of medicament dispersed substantially uniformly in the composition "Relatively high" viscosities range from about 400 to about 1000 cps when measured by the method disclosed in the specification

as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity	Upon application of shear force, the viscosity of the composition decreases sufficiently to allow the composition to flow freely through a pump orifice and break up into a fine mist that can infiltrate and deposit on mucosal regions "Relatively low" viscosities range from about 50 to about 200 cps when measured by the method disclosed in the specification
in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity	Upon removal of shear force and in relatively unstressed form following deposition on mucosal surfaces, the viscosity of the composition increases to a relatively high value such that the composition is retained on the mucosal surfaces on which it is deposited and resists being swept away by mucocillary clearance forces, and reverts to the viscosity in unsheared form "Mucocillary forces" are those that cause mucocillary clearance

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